JUL 25 2005

510(k) Summary
for
TerraQuant MQ2000 Laser Therapy Device

1. SPONSOR

Escada International, Inc.
27100 Richmond Road
Solon, Ohio 44139

Contact Person: Max Kanarsky
Telephone: 440-542 0762

Date Prepared: March 10, 2005

2. DEVICE NAME

Proprietary Name: TerraQuant MQ2000 Laser Therapy Device
Common/Usual Name: heating lamp
Classification Name: Infrared lamp

3. PREDICATE DEVICES

Quantum WARP 10 Light Delivery System – K032229

4. DEVICE DESCRIPTION

The TerraQuant MQ2000 is a non-invasive pain therapy system, which utilizes heating lamps consisting of laser, infrared, and visible red light emitting diodes (LED). It combines the clinically accepted therapeutic treatment of numerous predicate light therapy systems currently in commercial distribution into one complete, compact system.

The TerraQuant MQ2000 system consists of a desktop control unit, a hand-held emitter from which the laser and other radiances are released, and a 110 V power adaptor. The laser and light therapy releases radiation with wavelengths that fall within the range as defined in 21 CFR 890.5500 for an infrared lamp.

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5. INTENDED USE

The TerraQuant MQ2000 Laser Therapy Device is a non-invasive infrared lamp intended to provide topical heating. The Terraquant MQ2000 in indicated for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The TerraQuant MQ2000 device and the predicate device are substantially equivalent in intended use in that they are both heating lamps intended for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated. The proposed device and predicate devices are intended to provide relief to various areas of the body depending on the site of pain.

The proposed TerraQuant MQ2000 Laser Therapy System and the predicate devices are also substantially equivalent in technological characteristics in that they all consist of hand-held, heating infrared lamps that deliver low level laser to various anatomic areas.

Name of Manufacturer: Escada International, Inc.
Laser Model Name and Number: Terraquant MQ2000

Laser Type: (Circle all that apply)
Alexandrite, Argon, CO2, Copper-Vapor, Diode, Dye, Nd:YAG, Erbium, Hol: YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other _____

Indications in this application:

The TerraQuant MQ2000 is a non-invasive infrared lamp intended to provide topical heating. The TerraQuant MQ2000 is indicated for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

FDA Document Control Number: K043055

FDA Product Code: 79GEX

Reviewer Computer Initials: CYH

Date of Clearance Letter: 07/18/05

Basis of Approval: (Circle all that apply)
Predicate Device (PD), Clinical Data (CD), Animal Data (AD), Specifications (SPECS), Bench Test Data (BTD), Historical Information (HI), Other _____

Description of Laser:
Operation Modes: (Circle all that apply)
CW, Pulsed, Q-Switched, Mode Locked, Contact, Free Beam, Other _____

Wavelength in Nanometers: 900, 860-960, 600-700

Power/Energy Range (Watts/Joules): 60-90 mW

Pulse Width:

Repitition Rate:

Delivery System: hand held emitter
Comments:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2005

Escada International, Inc.
c/o Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K043055
Trade/Device Name: TerraQuant MQ2000 Laser Therapy Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: July 5, 2005
Received: July 6, 2005

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043055

Device Name: TerraQuant MQ2000 Laser Therapy Device

Indications for Use:

The TerraQuant MQ2000 is a non-invasive infrared lamp intended to provide topical heating. The Terraquant MQ2000 is indicated for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

Prescription Use _____ AND/OR Over-the-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...sion Sign-Off)
...ision of General, Restorative
...d Neurological Devices
K043055